

Detailed Action

NOTICE OF ALLOWANCE

This action is in response to the amendment filed February 1, 2008. Applicant has cancelled claims 2-13 and 22-27, and amended Claims 1 and 14-15. All of the amendments have been thoroughly reviewed and entered. The previous rejections of claims 14-21 in the Office action mailed on November 1, 2007 are withdrawn in view of the amendments.

Priority

Applicant's claim for the benefit of the prior-filed U.S. Provisional Application 60/361,528, filed March 1, 2002 under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged.

Interview Summary

1. In a telephone interview with Applicant's representative, Mark Benedict, on April 8, 2008, the Examiner presented a new argument for lack of enablement of Claim 1 on the grounds that the method steps are incomplete and would not predictably and necessarily yield Applicant's inventive HEI-193 cells, deposited as ATCC Accession #PTA-4544.

The specification discloses that HEI-193 human Schwannoma cells are exceptionally abnormal, have diverse chromosomal complement, and manifest karyotypic and phenotypic traits that are not constant. The primary Schwannoma cells had already suffered genetic changes *in vivo* that transformed the cells from normal to neoplastic. Furthermore, once established *in vitro* and transfected with HPV E6 and E7 genes, the HEI-193 cells began to acquire additional, novel phenotypic properties before and after the respective M1 senescence and M2 immortalization crises, such as increasing morphological heterogeneity, changes in cell proliferation rates, variation in S100 marker expression, and genomic instability such as changes in chromosome number and type (pages 13-15).

The method steps of claim 1 are incomplete because they do not recite a selection step that allows the artisan to recapitulate the preamble "producing an isolated HEI-193 human schwannoma cell line...deposited as ATCC #PTA-4544". The claims require the use of a

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retroviral vector to introduce the immortalizing E6 and E7 genes into primary human vestibular Schwannoma cells. However, the specification does not disclose the retroviral integration site(s) and neither the claims nor the specification disclose how to target the retroviral vector(s) to integrate into the same location(s) and number found in HEI-193 human schwannoma cell line deposited as ATCC #PTA-4544. Thus, the claims are incomplete because an artisan performing the instantly claimed method steps would not reliably and predictably obtain the isolated HEI-193 human schwannoma cell line deposited as ATCC #PTA-4544. Rather, the artisan would obtain an immortalized human schwannoma cell line having distinctly different genomic constitutions, karyotype and phenotype.

The Examiner respectfully suggested that claim 1 may be cancelled so as to advance the allowance of claims 14-21.

In a telephone interview on April 10, 2008, Applicant's representative, Mark Benedict authorized the cancellation of Claim 1 without prejudice and the amendment to the specification to include a paragraph disclosing the application's continuity data.

Examiner's Amendment

2. **An Examiner's amendment to the record** appears below. Should the changes and/or additions be unacceptable to Applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Amendments to the Claims

Claim 1 is cancelled without prejudice.

Amendments to the Specification

3. The statement "This application is a 371 of PCT/US03/06314 filed on March 3, 2003 which claims benefit of the provisional application 60/361,528 filed on March 1, 2002, the

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contents of which are incorporated by reference in their entirety.” was inserted on page 1 after the Title “Human Schwannoma Cell Line” and before the heading “Background of the Invention”.

4. The following is an Examiner’s statement of reasons for allowance:

The Hung declaration under 37 CFR 1.132 filed October 4, 2007 has been considered and is sufficient to overcome the rejection of claims 14-21 based upon i) the claimed human cell line was and still is the first and only available human immortalized Schwannoma cell line (¶1), ii) as far back as 1990, up until the present invention in 2002, the scientific community working in the field of Schwann cell and schwannoma cell research was either unmotivated to try to make immortalized human Schwann or schwannoma cells or unsuccessful in doing so (¶5), and iii) since the publication in 2002 of the inventor’s manuscript describing the method of obtaining the first ever immortalized human schwannoma cell line, which was the basis of the present application, the Assignee of this application, House Ear Institute, obtained material transfer agreements from 18 research groups to deliver the sample of the claimed cell line (HEI-193) for their research (¶7).

The prior rejections of the claim 15-21 are withdrawn in light of Applicant’s amendments to limit the scope of the invention to an isolated HEI-193 human Schwannoma cell line actively expressing the E6 and E7 genes of human papilloma virus 16, deposited as ATCC Accession #PTA-4544.

The Examiner acknowledges the amendment to the specification on December 12, 2006, wherein the preferred cell line was deposited under the Budapest Treaty on July 11, 2002 with the American Type Culture Collection (10801 University Blvd., Manassas, VA) as ATCC #PTA-4544, thereby enabling the artisan to use the inventive cell line.

Any comments considered necessary by Applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin K. Hill, Ph.D./

Examiner, Art Unit 1633

/Joseph T. Woitach/

Supervisory Patent Examiner, Art Unit 1633